

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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11/8/05

IN RE APPLICANT : Jackowski et al.
INVENTION : Betaine/GABA Transport Protein
Biopolymer Marker Indicative of
Insulin Resistance /
SERIAL NUMBER : 09/992,067
FILING DATE : November 21, 2001
EXAMINER : Cheu, Changhwa J.
GROUP ART UNIT : 1641
OUR FILE NO. : 2132.100

CERTIFICATE UNDER 37 CFR 1.8(a)

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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to
represent the inventor's and assignee in the application entitled
"Betaine/GABA Transport Protein Biopolymer Marker Indicative of
Insulin Resistance", having U.S. Application Serial No. 09/992,067,
filed November 21, 2001.

2. In the Office Action mailed on September 08, 2005, claim 1 (as presented on July 12, 2005) was rejected under 35 USC 112, first paragraph, because the claimed invention allegedly contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the Examiner points to original Figure 1 containing the two samples from insulin resistance patients (lane 2 and 3 from the left of the figure). The Examiner asserts that the results of the photograph in original Figure 1 are "vague and fuzzy" with only one band (i.e., Band 3), corresponding to betaine/GABA transport protein fragment (SEQ ID NO:2), appearing on one of the insulin resistance patients (lane 2 of Figure 1); there is no band appearing on the second insulin resistance patient. The Examiner concludes there lacks consistency among the insulin resistance patients if the appearance of a fragment peptide (e.g, up-regulation) is significant and essential as a biomarker for insulin resistance.

3. Applicants respectfully disagree with the Examiner's interpretation of the results of the photograph in original Figure 1. Particularly, the Examiner's assertion regarding lane 2 is incorrect. The poor quality of the results shown in the gel electrophoresis in original Figure 1 may have caused the Examiner to misinterpret the results shown therein. Therefore, Applicants

have attached herewith a replacement Figure 1, which is a clearer copy of Figure 1 as originally filed and is provided to clarify the presence of Band 3 in the different insulin resistance patients.

4. The attached figure 1 was produced by scanning the original photograph of the gel at a higher resolution. No new matter has been added. The figure entitled "HiQ 1 -(Elution) Insulin Resistance vs. Normal" included herein represents Figure 1.

As shown in the attached replacement Figure 1 (as read from the left), lane 1 is reserved for low molecular weight standards. Lane 2 corresponds to a diabetes type I patient, not an insulin resistance patient as stated by the Examiner. Lanes 3 and 4 contain samples obtained from different insulin resistance patients. Lanes 5 and 6 contain sample from Type II diabetes patients. Lanes 7 thru 9 correspond to sample obtained from normal control patients and lane 10 is reserved for high molecular weight standards, as disclosed along the perimeters of the photograph in original Figure 1 and replacement Figure 1. Band 3 is clearly decipherable in both insulin resistance patients, lanes 3 and 4 (replacement Figure 1). Thus, contrary to the Examiner's assertion Figure 1 does demonstrate "up regulation" phenomena in the insulin resistance patients.

5. The gel shown in the attached figure does not represent new experimentation; it is merely a duplicate of the original gel

made at the time that the experiments described in the instant specification were first carried out.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

10/19/2005
Date

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